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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/019,966 | 05/01/2002 | Masataka Nadaoka | 2001-1915A | 6249 |
| 513 | 7590 | 12/10/2004 | EXAMINER | |
| WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | NGUYEN, BAO THUY L | |
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| | | | 1641 | |

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------|-------------------------------|--|
| Office Action Summary | Application No. 10/019,966 | Applicant(s) NADAOKA ET AL | |
| | Examiner Bao-Thuy L. Nguyen | Art Unit 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment filed on 27 October 2004 has been received. Claims 1-16 have been cancelled. Claims 17-27 have been added and are pending.
2. The submission is a substitute specification and abstract is acknowledged.
3. The text of those US codes not found in this office action may be found in a previous office action.
4. All rejections not reiterated herein below are withdrawn in view of the cancellation of claims 1-16.

Claim Rejections - 35 USC § 112

5. Claims 17-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is vague and indefinite because the relationship between the components in the inspection target solution and the marker reagent has not been properly defined. Therefore, it is unclear how the measurement of the marker reagents is related to the quality to quantity of the components in the solution.

It is also unclear how the marker reagent is immobilized in the second part of the development portion. What is in the second part of the development portion that allows it to immobilize the marker reagent?

Art Unit: 1641

Claim 17 is further confusing because there are two separate measuring steps that do not appear to relate to each other. It appears that a wherein clause should be added between the two measuring steps.

Claim 17 recites a step of correcting the measured bonding amount of the marker reagent *in response* to an unreacted marker reagent or those marker reagents that have eluted from the development portion but are not immobilized in the second part of the development portion. However, it is unclear what exactly is involved in this correction? Is a ratio being taken, a difference or a total of the marker reagent?

Claims 17-27 are vague and indefinite with respect to the recitation of the marker reagent that has been eluted from said first part of the development portion because it is unclear if this includes those that have been immobilized in the second part of the development portion. Claims 17 and 18 do not exclude the marker reagents that are in the second part of the development portion.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 17-27 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over DeLaCroix et al (US 5,206,177).

DeLaCroix discloses a device and method for detecting analytes from a sample comprising means for separating mobile detectable moiety from unreacted reaction component. The device comprises an optional sponge 13 which can be impregnated with a buffer, and may receive the sample being analyzed. The first zone 14 is positioned so that it receives sample which diffuses from sponge 13 when the sponge is used. Zone 14 contains a conjugate pad 15, and a matrix 16. Conjugate pad 15 contains the removable labeled analyte, labeled analyte analogue, or labeled binding partner. When the sample contacts this region, either by direct contact or by diffusion, the conjugate and the sample mix, and any reactions between analyte and binding partner take place. The mixture passes to matrix 16, which contains an immobilized form of a reagent. Generally the immobilized reagent is identical, or epitopically equivalent to the analyte being determined. When this is the case, the immobilized reagent must be present in an amount sufficient to bind essentially all of the labeled conjugate present in conjugate pad 15. This is necessary to provide for the situation where the sample contains none of the analyte being determined. In a displacement assay, conjugate pad 15 and matrix 16 will be of one piece because the immobilized reagent will already have bound to it the labeled analyte or analyte analogue. Second zone 19 contains two parts, but this is not necessarily so. Substrate pad 18 contains a substrate which reacts with the label on the labeled component to form a detectable signal. This may be, but need not be, an enzyme substrate. Trapper pad 20, which is key to the invention, is in fluid contact with the substrate pad 18, or, if 18 and 20 constitute one piece, this one piece second zone is in fluid contact with the first zone. The trapper pad 20 contains a

Art Unit: 1641

means, such as ionic exchange paper, which traps either the reaction product of the label and substrate, or unreacted substrate. Finally, in fluid contact with the second zone 19 is the waste pad 22, which is adapted for receiving excess fluid. Further, it absorbs any materials which may be removed when the test strip is washed. The waste pad 22 can, alternatively, be used as a measuring point. When separation of detectable moiety and unreacted reaction component takes place in the second zone 19, the element which is not trapped can be washed into the waste pad. This element, rather than the trapped element, can be measured as well as, or in preference to, the trapped element. See column 6, line 12 through column 7, line 9.

Even though DeLaCroix does not specifically recite correcting the measured amount of marker reagent in the detection zone, DeLaCroix is seen to anticipate the instant invention because the correcting step recited in the claim appears to be nothing more than taking an additional measurement of the marker reagent in another zone or those that are unreacted, both of these steps are taught by DeLaCroix.

8. Claims 17-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuo (EP 0 895 084 A2).

Kuo discloses a method and device for determination of an analyte in a sample of body fluid. The test strip comprises a matrix made of paper, nitrocellulose or nylon material (page 3, lines 43-50). The strip has a first region which contains mobile specific binding partner for the analyte which bears a detectable label such as gold sol or latex particles; a second region containing immobilized binding partner which is specific for an epitope of the analyte different than that to which analyte binding gold sol particles are specific; and a third region containing means for capturing the analyte/labeled specific binding partner complex which is not bound

Art Unit: 1641

in the second region (page 2, line 55 through page 3, line 6). The third region may also contain an immobilized antibody against the labeled binding partner (e.g. anti-mouse IgG when the labeled binding partner is an antibody). See page 4, lines 7-12. Kuo also teaches an absorbent pad which serves to absorb the liquid that migrates past the various zones of the test strip (page 7, lines 56-57). In use, sample is applied to the test strip at an application point, (area 1 of figure 1) and allowed to migrate to the various zones of the test strip. Signals from the detectable label in the second region (sample capture zone) and from the detectable label in the third region (control capture zone) are measured using an optical detector (page 2, lines 19-20), and the ratios of these signals is determined and related to the amount of the analyte in the sample. Kuo teaches that such a determination provides the advantage of an increase in accuracies, because it corrects for inaccuracies in labeled conjugate deposition and/or non-uniform flow through the matrix (page 4, lines 6-17). Kuo also teaches a method in which the summation of the signal from both the sample capture and control capture zones is taken, and the ratio of the signal in the sample capture zone and the sum is used to determine the amount of analyte (page 4, lines 34-37). Kuo teaches that the test strip and method disclosed may be adapted to determine various types of analytes such as PSA and hCG (page 7, lines 13-21) in body samples such as serum.

Response to Arguments

9. Applicant's arguments filed 27 October 2004 have been fully considered but they are not persuasive.

Art Unit: 1641

Applicant argues that DeLaCroix does not disclose that a measurement value of the element which is trapped by the trapper pad 20 is "corrected" by a measurement value of the element which is not trapped. Thus, DeLaCroix does not anticipate the pending claims.

While it may be true that DeLaCroix does not specifically recite a correcting step, it is also true that the pending claims do not clearly state how the correcting step is performed. As stated above, the correcting step is nothing more than taking a measurement of unreacted marker reagents and a measurement of marker reagents in a zone that is different from the detection zone. Both of these measurement steps are taught by DeLaCroix, therefore, DeLaCroix anticipates, or in the alternative, makes obvious the instant claims.

Conclusion

10. No claims are allowed.

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,436,721 B1

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory

Art Unit: 1641

period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 8:00 a.m. -3:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641

12/7/04